K033183 1/2

APR 1 5 2004

510(k) SUMMARY

CureLight's ReClear™

CureLight Ltd.
2 Ha'ilan Street
Northern Industrial Zone, POB 247
Or Akiva 30600, Israel.

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Contact Person: Dr. Yoram Harth

Date Prepared: **September 23rd, 2003**

Name of Device and Name/Address of Sponsor

ReClear™ Phototherapy Device, Model FGCM0012

CureLight Ltd.
2 Ha'ilan Street
Northern Industrial Zone, POB 247
Or Akiva 30600, Israel

Common or Usual Name

Light Therapy Device

Classification Name

Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology

Predicate Devices

Light Force Therapy's SuperNova/Acubeam (K001179), MedX Health

K033193 2/2

Corp. 's MedX 1000 series (K 020017), C&H international Inc.'s TDP lamp (K020851), and Curelight's iClear Phototherapy System (K030338).

Intended Use

The ReClear™ Phototherapy System ("ReClear™ ") is intended to provide phototherapeutic light to the body. The ReClear™ is specifically indicated to emit visible blue/violet light for treatment of moderate inflammatory acne vulgaris. It also emits infrared light energy for the temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.

Technological Characteristics

The ReClear emits in the range of visible blue/violet light (405-420nm) and infrared light (850 nm to 900 nm) with a fluency of light up to 200mW/cm^2. The system also includes an optical system for controlling spectra and beam parameters of the light source, a mechanical fixture for holding the light source at an adjustable distance and direction in relation to the skin treatment area, and a timer unit to control the duration of the emitted radiation.

Substantial Equivalence

The CureLight ReClear™ is a modification to the iClear™ that has already been cleared by FDA to provide phototherapeutic light to the body. The ReClear™ blue/violet light mode has the same characteristics and technology as CureLight's iClear (K030338). In contrast to the iClear that is intended to treat inflammatory acne lesions, the ReClear™ emits also infrared light that is intended to temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis. The ReClear™ infrared mode is substantially equivalent to Light Force Therapy, Acubeam (K001179), and MedX Health Corp. , MedX 1000 series , (K020017) and C&H International Inc.'s TDP lamp (C&H international Inc.) (K020851) all of which FDA has already cleared for the same intended use and indications. Thus, ReClear™ is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2004

CureLight Ltd
C/o Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K033183
Trade/Device Name: ReClear Phototherapy System
Regulation Number: 21 CFR 878.4810, 21 CFR 890.5500
Regulation Name: Laser surgical instrument for use in general and plastic surgery and Dermatology, Infrared lamp
Regulatory Class: II
Product Code: GEX, ILY
Dated: February 5, 2004
Received: February 5, 2004

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K033183

Device Name: ReClear Phototherapy System

Indications for Use:

The ReClear™ Phototherapy System ("ReClear™ ") is intended to provide phototherapeutic light to the body. The ReClear™ is specifically indicated to emit visible blue/violet light to treat moderate inflammatory acne vulgaris and IR light energy for the temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness and relaxation of muscles; for muscle spasms, minor pain and stiffness associated with arthritis.

Prescription Use √ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(Optional Format 2003)

510(k) Number K033183